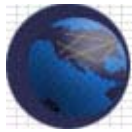




**Data Sharing and Intellectual Capital Working Group Teleconference**

<b>August 5, 2004</b>	2:00 pm EDT
<b>Attendees:</b>	<p><i>Attendees:</i></p> <p>Fox Chase: Amin Chisti</p> <p>Fred Hutchinson: Bob Robbins; IP POC: Paul J. Brynes</p> <p>Jackson Labs: Carol Bult; IP POC: David Einhorn</p> <p>Jefferson University: Jack London</p> <p>Oregon Health and Science University: Ed Quick; IP POC - Mary Foley</p> <p>University of Iowa: Terry Braun; IP POC – Daniel Happe</p> <p>University of Minnesota – Don Connelly</p> <p>U. Penn – Howard Bilofski; IP POC - Terry J. Fadem</p> <p>Washington University—Siteman: Mark Watson</p> <p>NCI - Wendy Patterson; Leslie Derr</p> <p>BAH - Phan Winter; Arumani Manisundaram; Mike Keller</p>
<b>Introduction</b>	<p>Wendy Patterson opened the meeting and reviewed the agenda. She proposed discussing the survey first to maximize the time of the IP POCs in attendance.</p>
<b>Update on Survey Development</b>	<p><b><u>Comments from IP POCs:</u></b></p> <p>Terry Fadem (University of Pennsylvania) made several recommendations. First, he thought that the survey should define the term Agreements since institutions enter into many types of agreements, such as material transfer agreements, nondisclosure agreements, clinical trial agreements. Without definition the use of this word could be confusing and could lead to a low response rate. Second, the offices responsible for negotiating and keeping records of particular agreements may be in different places within an institution due to the different issues raised by such agreements. Therefore, the survey respondent may need to seek input from the institution's General Counsel's office, the Technology Transfer office, or other appropriate offices. Third, he recommended asking that responses be measured by percentages of</p>



agreements in different categories rather than in absolute numbers. Moreover, he suggested asking respondents to answer questions based on the total number of institutions with which they have agreements, which is a far easier number for respondents to generate and for the DSIC WG to analyze. As presently drafted, knowledge of each agreement is necessary in order to answer many of the questions. An institution may have hundreds of Material Transfer Agreements and without going through them all, it is not possible to tell how many cover specimens, reagents or other materials.

David Einhorn (Jackson Laboratory) also expressed concern about having to come up with absolute numbers in the survey, which he thought would be a Herculean task. Instead, he suggested focusing on the ultimate issue, which is the extent of the impediments to sharing data.

Mary Foley (Oregon Health Sciences University) noted that her institution is concerned about the de-identification of patient information in view of the Oregon Genetic Privacy Act requirements. It was noted that different requirements imposed by individual state laws may present issues for caBIG participants.

Jon Kratochvil (Siteman/Washington University) was unable to participate but provided comments to Phan Winter, who relayed his input to the group. His response was very similar to the comments described above. It would be impossible to arrive at absolute numbers of agreements for his center. Aside from the enormous number of documents that he would have to find and review, his office does not have access to all relevant documents mentioned in the survey. Different types of agreements are handled by different offices. His general view is that the DSIC WG's goal of reducing restrictions on data sharing is important but seems impossible to achieve with the survey in its current form. Given the trend of industry becoming more aggressive in claiming rights to data in any agreement, he believes it is critical to protect institutions' rights to share data.

When asked how much effort would be required to complete the survey, the IP POCs stated that by moving to percentages rather than absolute numbers, it would be feasible to respond within a few hours and get credible information that would identify the pressing impediments. They stressed the importance of having the principal respondents contact the relevant offices within their institutions and describe those



sources.

### **DSIC WG discussion of IP POC comments**

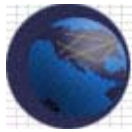
In general, the group agreed with the suggestion that survey respondents estimate percentages of impediments rather than absolute numbers of types of agreements. Mark Watson reiterated the importance of assessing the magnitude of the problem quantitatively (1% vs. 90%) but agreed that the assessment could be made by using estimates.

Amin Chisti asked about actions to be taken after collection of the survey responses: What is the process for summarizing responses? Should the group follow up with interviews to clarify extent of actual impediments? The group responded favorably to the idea of follow up interviews.

Wendy Patterson noted that it will be important to get pharmaceutical companies involved in the discussion of these issues. She reported a recent meeting with members of the Clinical Trials WS who discussed the idea of organizing a one-day face-to-face meeting of the stakeholders in the clinical trials process to discuss the importance of sharing data. Since the meeting will address issues of central importance to the DSIC WG, she will involve the group in the agenda development and will let the IP POCs know about this meeting once it is scheduled. Terry Fadem and Bob Robbins indicated that they have invitees from the academic community to recommend and will forward contact information to Phan Winter.

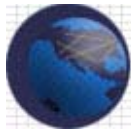
Bob Robbins noted that there are various problems with different paths taken to reduce sharing impediments, and given the complexity of daring sharing issues, he thought that the group may need to prioritize its concerns. He stated that the caBIG community should promote data sharing in ways that protect participants from liability. (Ed Quick added that making sure that caBIG complies with any pre-existing rules on data sharing will protect the grid from shut-downs due to violations of such rules.) He thought that if properly instructed, the Architecture WS could devise a system to protect data so that it is not accidentally shared, which could help with future contract negotiations. Finally, he emphasized the importance of arriving at win-win solutions when interacting with pharma on these issues.

Howard Bilofski stated that the DSIC WG should not be concerned about the complexity created by data sharing



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	<p>restrictions and the Architecture WS could work with this group to develop workable standards. Arumani Manisundaram responded that the Architecture WS welcomes guidelines from the DSIC WG that he can take back to the developers. Mark Watson recommended that the DSIC WG take on an action item of working with the Architecture WS to develop a model of data sharing possibilities that will support restrictions on sharing and protect intellectual property. Bob Robbins thought that in developing standards, the DSIC WG might be able to find ways to segregate data subject to third party rights and perhaps help caBIG participants clarify ambiguous contracts.</p> <p>Wendy Patterson summarized by stating (this does not follow from previous conversation. Wendy Patterson summarized the action items ...?) that the DSIC WG should reformat the survey based on the input from the IP POCs and then send it out to all caBIG centers' IP POCs. After collecting the responses, the group should start working on drafting working guidelines and model agreement terms for data sharing, which should then be circulated to the DSIC WG IP POCs.</p>
<b>Report from Liaisons</b>	<p>Due to time constraints, this agenda item was deferred until the next scheduled teleconference.</p>
<b>DSIC One-Year Goal</b>	<p>The DSIC WG agreed upon the following objectives to be completed a year after commencement of caBIG:</p> <ul style="list-style-type: none"><li>• Develop model agreement language and general guidelines for sharing data within the caBIG community</li><li>• Collaborate with the Architecture WS to develop concrete data sharing standards – e.g, a process model, codes, etc.</li><li>• Address IRB and patient confidentiality issues; build on the experience of other research groups such as the Biomedical Informatics Research Network (BIRN) and the Washington University's automated system for IRBs</li><li>• Communicate with industry and other stakeholders in a structured dialogue to discuss data sharing standards that are developed and accepted within caBIG</li></ul>
<b>Items for Next Teleconference:</b>	<p>Most of the core group is available for August 19<sup>th</sup> teleconference.</p>



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August 19th		<ul style="list-style-type: none"><li>Review revised survey</li></ul>		
Action Items:	Name Responsible	Action Item	Date Due	Notes
	Phan/Wendy	Revise survey	8/16/2004	
	Phan	Send one-year plan to Strategic Planning		Pending DSIC approval of summary
	Phan	Follow up with responses promised by IP contacts	8/12/2004	